



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Mohamed Attawia, Hassan Serhan, Thomas M. DiMauro, Melissa Grace and David Urbahns

Application No.: 10/714,594 Group Art Unit: 1649  
Filed: November 14, 2003 Examiner: Steven H. Standley

Confirmation No.: 3230

Title: AUTOLOGOUS TREATMENT OF DEGENERATED DISC WITH CELLS

CERTIFICATE OF MAILING OR TRANSMISSION	
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March 15, 2006	<i>Linda M. Byrnes</i>
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Linda M. Byrnes	
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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

☐ under 37 CFR 1.129(a), or  
(First/Second submission after Final Rejection)

☒ under 37 CFR 1.97(b), or  
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).

☐ under 37 CFR 1.97(c) together with either:  
☐ a Statement under 37 CFR 1.97(e), as checked below, or  
☐ a \$180.00 fee under 37 CFR 1.17(p), or  
(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)

☐ under 37 CFR 1.97(d) together with:  
☐ a Statement under 37 CFR 1.97(e), as checked below, and  
☐ a \$180.00 fee under 37 CFR 1.17(p), or  
(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)

☐ under 37 CFR 1.97(i):  
Applicant requests that the IDS and cited reference(s) be placed in the application file.  
(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
  - ☒ Copies of the cited references are enclosed. [AN-AM4 & AT5-AY13]
    - ☒ Copies of issued U.S. patents and published U.S. applications are not required and are not being provided.
  - ☐ Copies of the cited references are enclosed except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed. [The earlier application contains copies of the cited references.]
  - ☐ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.
  - ☐ The "concise explanation" requirement (non-English references) for reference(s) [ ] under 37 CFR 1.98(a)(3) is satisfied by:
    - ☐ the explanation provided on the attached sheet.
    - ☐ the explanation provided in the Specification.
    - ☐ submission of the enclosed International Search Report.
    - ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
    - ☐ the enclosed English language abstract.

- ☐ Applicant requests that the following non-published pending applications be considered:  
(Affix a label or apply the stamp "Non-Published IDS Reference - Do Not Scan" to the front of each unpublished pending appl'n.)

Examiner's  
Initials

\_\_\_\_ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]  
\_\_\_\_ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]  
\_\_\_\_ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]

\_\_\_\_\_  
Examiner

\_\_\_\_\_  
Date

- ☐ A copy of each above-cited application, including the current claims, is enclosed, except any application filed on or after June 30, 2003, which has been scanned into the PTO's Image File Wrapper (IFW) system and is available to the examiner.
- ☐ A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

- ☐ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.
- ☐ Please charge Deposit Account 08-0380 in the amount of \$[ ]. A copy of this Statement is enclosed.
- ☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

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Dated:

March 15, 2006

PTO-1449 REPRODUCED

ATTORNEY DOCKET NO.  
3518.1012-005APPLICATION NO.  
10/714,594SUPPLEMENTAL  
INFORMATION DISCLOSURE STATEMENT  
IN AN APPLICATION

March 15, 2006

FIRST NAMED INVENTOR  
Mohamed AttawiaFILING DATE  
November 14, 2003EXAMINER  
Standley, Steven H.CONFIRMATION NO.  
3230GROUP  
1649

(Use several sheets if necessary)

## U.S. PATENT DOCUMENTS

EXAM- INER INI- TIAL	REF. NO.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
	AH	4,427,649	01-24-1984	Dingle, <i>et al.</i>
	AI	5,095,037	03-10-1992	Iwamitsu, <i>et al.</i>
	AJ	5,116,964	05-26-1992	Capon, <i>et al.</i>
	AK	5,225,538	07-06-1993	Capon, <i>et al.</i>
	AA2	5,231,024	07-27-1993	Moeller, <i>et al.</i>
	AB2	5,270,300	12-14-1993	Hunziker
	AC2	5,368,841	11-29-1994	Trauner, <i>et al.</i>
	AD2	5,447,851	09-05-1995	Beutler, <i>et al.</i>
	AE2	5,510,370	04-23-1996	Hock
	AF2	5,656,272	08-12-1997	Le, <i>et al.</i>
	AG2	5,728,396	03-17-1998	Peery, <i>et al.</i>
	AH2	5,833,984	11-10-1998	Eibl, <i>et al.</i>
	AI2	5,942,499	08-24-1999	Radomsky
	AJ2	5,965,583	09-12-1999	Beers, <i>et al.</i>
	AK2	6,277,969	08-21-2001	Le, <i>et al.</i>
	AA3	6,284,471	09-04-2001	Le, <i>et al.</i>
	AB3	6,294,170	09-25-2001	Boone, <i>et al.</i>
	AC3	6,419,944	07-16-2002	Tobinick
	AD3	6,541,477	04-01-2003	Goehring, <i>et al.</i>
	AE3	6,554,830	04-29-2003	Chappius
	AF3	6,590,081	07-08-2003	Zhang
	AG3	6,623,472	09-23-2003	Reinecke, <i>et al.</i>
	AH3	6,713,246	03-30-2004	Reinecke, <i>et al.</i>
	AI3	US 2001/0006948 A1	07-05-2001	Kang, <i>et al.</i>
	AJ3	US 2001/0016195 A1	07-05-2001	Tobinick

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**SUPPLEMENTAL  
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ATTORNEY DOCKET NO.  
3518.1012-005

APPLICATION NO.  
10/714,594

FIRST NAMED INVENTOR  
Mohamed Attawia

FILING DATE  
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Standley, Steven H.

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## U.S. PATENT DOCUMENTS

[illegible]

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	EXAMINER Standley, Steven H.		CONFIRMATION NO. 3230	GROUP 1649

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER Country Code-Number-Kind Code (if known)	DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT	TRANSLATION YES	NO
	AN	EP 0 218868 A2	04-22-1987	New York Blood Center, Inc.		
	AO	EP 0 288 088 B1	10-26-1988	Teijin Limited		
	AP	EP 0 438234 A1	07-24-1991	Kita		
	AQ	EP 0 950417 A2	02-15-1999	Pfizer Products, Inc.		
	AL2	EP 1 133995 A2	09-19-2001	Synergen, Inc.		
	AM2	EP 1 153607 A2	11-14-2001	Dunn		
	AN2	WO 01/85179 A2	11-15-2001	Clemson University		
	AO2	WO 02/057240 A1	07-25-2002	Ortho McNeil Pharmaceutical, Inc.		
	AP2	WO 02/100387 A1	12-19-2002	A+ SCIENCE INVEST AB		
	AQ2	WO 03/000190 A2	01-03-2003	DePuy		
	AL3	WO 91/02078 A1	02-21-1991	Peptide Technology LTD		
	AM3	WO 92/07076 A1	04-30-1992	The Charring Cross Sunley Research Centre		
	AN3	WO 92/16553 A1	10-01-1992	New York University and Centocor, Inc.		
	AO3	WO 93/16099 A2	08-19-1993	Biopharm Gesellschaft Zur Biotechnologischen Entwicklung Von Pharmaka MBH		
	AP3	WO 97/28828 A1	08-14-1997	Amgen Boulder, Inc.		
	AQ3	Intentionally Omitted				
	AL4	WO 98/24477 A1	06-11-1998	Amgen, Inc.		
	AM4	WO 99/45923 A1	09-16-1999	Merck & Co., Inc.		

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
AT5	Abstracts of the N. American Spine Society 17 Annual Meeting, Montreal, Canada, October 29 through November 2, 2002, <i>The Spine Journal</i> , 2(Suppl.). 49S-50S (2002).	
AU5	Allai, F., <i>et al.</i> , "Increase in Bone Mineral Density of Patients with Spondyloarthropathy Treated With Anti-Tumor Necrosis Factor $\alpha$ ," <i>Ann. Rheum. Dis.</i> , 62:347-349 (2003).	
AV5	Andonopoulos, A.P., <i>et al.</i> , "Intra-articular Anti-Tumor Necrosis Factor $\alpha$ Antibody in Recalcitrant Arthritis of Behçet's Disease," <i>Clinical and Experimental Rheumatology</i> 21(4 Suppl 30): S-57-S58 (July-August 2003).	
AW5	Aoki, Y., <i>et al.</i> , "Local Application of Disc-Related Cytokines on Spinal Nerve Roots," <i>Spine</i> , 27(15): 1614-1617 (2002).	
AX5	Ariga, K., <i>et al.</i> , "Mechanical Stress-Induced Apoptosis of Endplate Chondrocytes in Organ-Cultured Mouse Intervertebral Discs," <i>Spine</i> , 28(14): 1528-1533 (2003).	
AY5	Ashkenazi, A., <i>et al.</i> , "Protection Against Endotoxic Shock by a Tumor Necrosis Factor Receptor Immunoaderin," <i>Proc. Natl. Acad. Sci. USA</i> , 88, pp. 10535-10539.	
AZ5	Baker, D., <i>et al.</i> , "Control Established Experimental Allergic Encephalomyelitis by Inhibition of Tumor Necrosis Factor (TNF) Activity Within the Central Nervous System using Monoclonal Antibodies and TNF Receptor-Immunoglobulin Fusion Proteins," <i>Eur. J. Immunol.</i> , 24:2040-2048 (1994)	
AR6	Biskobing, D. M., "Novel Therapies for Osteoporosis," <i>Expert Opinion Invest. Drugs</i> , 12(4): 611-621 (2003).	
AS6	Bokarewa, M., <i>et al.</i> , "Local Infusion of Infliximab for the Treatment of Acute Joint Inflammation," <i>Ann. Rheum. Dis.</i> , downloaded from ard.bmjournals.com on 30 November 2005, <a href="http://www.annrheumdis.com">www.annrheumdis.com</a> 62:783-784 (2003).	
AT6	Boehm, <i>et al.</i> , "New Inhibitors of p38 Kinase," <i>Exp. Opin. Ther. Patents</i> , 10(1):25-37 (2000).	
AU6	Braun, J. and Sieper J., "Overview of The Use of The Anti-TNF Agent Infliximab in Chronic Inflammatory Diseases," <i>Expert Opin. Biol. Ther.</i> 3(1):141-168 (2003).	
AV6	Braun, J., <i>et al.</i> , "Anti-Tumour Necrosis Factor $\alpha$ Therapy for Ankylosing Spondylitis: International Experience," <i>Ann. Rheum. Dis.</i> , 61(Suppl. III):iii51-iii60 (2002).	

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	AW6	Bringman, T.S. <i>et al.</i> , "Monoclonal Antibodies to Human Tumor Necrosis Factors Alpha and Beta: Application for Affinity Purification, Immunoassays, and as Structural Probes," <i>Hybridoma</i> , 6(5):489-507 (1987).
	AX6	Brown, K., <i>et al.</i> , "Gelatin/Chondroitin 6-Sulfate Microspheres for the Delivery of Therapeutic Proteins to the Joint," <i>Arthritis. &amp; Rheum.</i> , 41(12):2185-2195 (1998).
	AY6	Burke, J.G., <i>et al.</i> , "Intervertebral Discs Which Cause Low Back Pain Secrete High Levels of Proinflammatory Mediators," <i>J. Bone Joint Surg. [Br]</i> 84-B, 196-201 (2001).
	AZ6	Butler, D. <i>et al.</i> , "TNF Receptor Fusion Proteins are Effective Inhibitors of TNF-Mediated Cytotoxicity on Human KYM-1D4 Rhabdomyosarcoma Cells," <i>Cytokine</i> , 6(6):616-623 (1994).
	AR7	Capon, D. <i>et al.</i> "Designing CD4 Immuno adhesins for AIDS Therapy," <i>Nature</i> , 337:525-531 (1989).
	AS7	Cardone, D. A., <i>et al.</i> , "Diagnostic and Therapeutic Injection of the Hip and Knee," <i>Am. Fam. Physician</i> , 67(10): 2147-2152 (2003).
	AT7	Chae, H.J. <i>et al.</i> , "The p38 Mitogen-Activated Protein Kinase Pathway Regulates Interleukin-6 Synthesis in Response to Tumor Necrosis Factor in Osteoblasts," <i>Bone</i> , 28(1): 45-53 (2001).
	AU7	Cirillo <i>et al.</i> , "The Non-Diaryl Heterocycle Classes of p38 MAP Kinase Inhibitors," <i>Current Topics in Medicinal Chemistry</i> , 2: 1021-1035 (2002).
	AV7	Conti, F., <i>et al.</i> , "Successful Treatment With Intraarticular Infliximab for Resistant Knee Monarthritis in a Patient With Spondylarthropathy," <i>Arthritis &amp; Rheumatism</i> , 52(4): 1224-1226 (2005).
	AW7	Corcoran, A.E. <i>et al.</i> , "Characterization of Ligand Binding by the Human p55 Tumour-Necrosis-Factor Receptor," <i>Eur. J. Biochem.</i> , 223:831-840 (1994).
	AX7	Crandall, C., "Combination Treatment of Osteoporosis: A Clinical Review," <i>J. of Women's Health &amp; Gender-Based Medicine</i> , 11(3):211-224 (2002).
	AY7	Dayer, J.M., "The Pivotal Role of Interleukin-1 in the Clinical Manifestations of Rheumatoid Arthritis," <i>Rheumatology, Oxford Univeristy Press, London, GB</i> , 42(Suppl 2):ii03-ii10 (2003).
	AZ7	DeSantis, A. and Buchman, A., "Current and Emerging Therapies in Osteoporosis," <i>Expert Opin. Pharmacother.</i> , 3(7):835-843 (2002).

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
AR8	Diwan, A. D., <i>et al.</i> , "Current Concepts in Intervertebral Disk Restoration," <i>Tissue Engineering in Orthopedic Surgery</i> , 31(3):453-464 (2000).	
AS8	Engelmann, H. <i>et al.</i> , "Two Tumor Necrosis Factor-Binding Proteins Purified From Human Urine," <i>J. Biol. Chem.</i> , 265(3):1531-1536 (1990).	
AT8	Ezra, A., and Golomb, G., "Administration Routes and Delivery Systems of Bisphosphonates for the Treatment of Bone Resorption," <i>Adv. Drug Del. Rev.</i> , 42:175-195 (2000).	
AU8	Fendly <i>et al.</i> , "Murine Monoclonal Antibodies Defining Neutralizing Epitopes on Tumor Necrosis Factor," <i>Hybridoma</i> , 6:359-370 (1987).	
AV8	Gabay, C., "IL-1 Trap," <i>Curr. Opin. Invest. Drugs, Curr. Drugs, London, GB</i> , 4(5):593-597 (2003).	
AW8	Goodman, S. <i>et al.</i> , "Effects of Local Infusion of TGF $\beta$ on Bone Ingrowth in Rabbit Chambers," <i>J. Biomed. Mat. Res. (Appl Biomater)</i> , 53:475-479 (2000).	
AX8	Gordon, J. L., <i>et al.</i> , "Metalloproteinase Inhibitors as Therapeutics," <i>Clin. Exp. Rheumatol.</i> , 11(Suppl. 8): S91-S94 (1993).	
AY8	Goupille, P., <i>et al.</i> , "Matrix Metalloproteinases The Clue to Intervertebral Disc Degeneration?," <i>Spine</i> , 23(14): 1612-1626 (1998).	
AZ8	Hirai, M. <i>et al.</i> , "Production and Characterization of Monoclonal Antibodies to Human Tumor Necrosis Factor," <i>J. Immunol. Meth.</i> , 96:57-62 (1987).	
AR9	Hunter, C. J., <i>et al.</i> , "Functional Behaviour of Notochordal Cell Clusters in the Canine Nucleus Pulposus: Cell Communication and Survival," 70, <i>Abstracts of the 30th Annual Meeting of the International Society for the Study of the Lumbar Spine</i> , Vancouver, Canada (May 2003).	
AS9	Hydrogels, <i>Encyclopedia of Polymer Science and Technology</i> , (Wiley and Sons, 2003).	
AT9	Johnson, W.H., <i>et al.</i> , "Collagenase Inhibitors: Their Design and Potential Therapeutic Use," <i>J. Enzyme Inhib.</i> , 2:1-22 (1987).	
AU9	Karppinen, J., <i>et al.</i> , "Tumor Necrosis Factor- $\alpha$ Monoclonal Antibody, Infliximab, Used to Manage Severe Sciatica," <i>Spine</i> , 28(8):750-754 (2003).	

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AV9		Kawakami, M., <i>et al.</i> , "Possible Mechanism of Painful Radiculopathy in Lumbar Disc Herniation," <i>Clin. Orthop.</i> 351:241-251(1998).
AW9		Kimble, R.B. <i>et al.</i> , "Estrogen Deficiency Increases the Ability of Stromal Cells to Support Murine Osteoclastogenesis Via an InterLeukin-1 and Tumor Necrosis Factor-Mediated Stimulation of Macrophage Colony-Stimulating Factor Production," <i>J. Biol. Chem.</i> 271(46):28890-28897 (1996).
AX9		Kimble, R.B. <i>et al.</i> , "The Functional Block of TNF but Not of IL-6 Prevents Bone Loss in Ovariectomized Mice," <i>J. Bone Min. Res.</i> , 12(6):935-941 (1997).
AY9		Koch, H. <i>et al.</i> , "Spontaneous Secretion of Interleukin 1 Receptor Antagonist (IL-1Ra) by Cells Isolated From Herniated Lumbar Discal Tissue After Discectomy," <i>Cytokine</i> , 10(9): 703-705 (1998).
AZ9		Kolls, J. <i>et al.</i> "Prolonged and Effective Blockade of Tumor Necrosis Factor Activity Through Adenovirus-Mediated Gene Transfer," <i>Proc. Natl. Acad. Sci. USA</i> , 91:215-219 (1994).
AR10		LaVan, D. A., <i>et al.</i> , "Small-Scale Systems for <i>in vivo</i> Drug Delivery," <i>Nature, Biotechnology</i> , 21(10):1184-1191 (2003).
AS10		Lee, <i>et al.</i> , "Inhibition of p38 MAP Kinase as a Therapeutic Strategy," <i>Immunopharmacology</i> , 47: 185-201 (2000).
AT10		Lehman, T. J. A., <i>et al.</i> , "Thalidomide Therapy for Recalcitrant Systemic Onset Juvenile Rheumatoid Arthritis," <i>J. Pediatrics</i> , 140(1):125-127 (2002).
AU10		Lesslauer, W., <i>et al.</i> , "Recombinant Soluble Tumor Necrosis Factor Receptor Proteins Protect Mice from Lipopolysaccharide-Induced Lethality," <i>Eur. J. Immunol.</i> , 21:2883-2886 (1991).
AV10		Liang, C.-M., <i>et al.</i> , "Production and Characterization of Monoclonal Antibodies Against Recombinant Human Tumor Necrosis Factor/Cachectin," <i>Biochem. Biophys. Res. Comm.</i> 137(2):847-854 (1986).
AW10		Loetscher, H. <i>et al.</i> , "Molecular Cloning and Expression of the Human 55 kd Tumor Necrosis Factor Receptor," <i>Cell</i> , 61:351-359 (1990).
AX10		Maeda, S. and Kokubun, S., "Changes With Age in Proteoglycan Synthesis in Cells Cultured <i>In Vitro</i> From the Inner and Outer Rabbit Annulus Fibrosus," <i>Spine</i> , 25(2):166-169 (2000).

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AY10	Meager, A. <i>et al.</i> , "Preparation and Characterization of Monoclonal Antibodies Directed Against Antigenic Determinants of Recombinant Human Tumour Necrosis Factor (rTNF)," <i>Hybridoma</i> , 6(3):305-311 (1987).	
AZ10	Möller, A. <i>et al.</i> , "Monoclonal Antibodies to Human Tumor Necrosis Factor $\alpha$ : In Vitro and In Vivo Application," <i>Cytokine</i> 2(3):162-169 (1990).	
AR11	Molloy, T., <i>et al.</i> , "The Roles of Growth Factors in Tendon and Ligament Healing," <i>Sports Med.</i> , 33(5): pp.381-394 (2003).	
AS11	Müller, R. "Determination of Affinity and Specificity of Anti-Hapten Antibodies by Competitive Radioimmunoassay," <i>Meth. Enzymol.</i> , 92:589-601 (1983).	
AT11	Nakamura, K. <i>et al.</i> , "Local Application of Basic Fibroblast Growth Factor into the Bone Increases Bone Mass at the Applied Site in Rabbits," <i>Arch. Orthop. Trauma Surg.</i> , 115(6):344-346 (1996).	
AU11	Nakamura, K. <i>et al.</i> , "Stimulation of Endosteal Bone Formation by Local Intraosseous Application of Basic Fibroblast Growth Factor in Rats," <i>Rev. Rhum. [Engl. Ed.]</i> , 64(2):101-105 (1997).	
AV11	Nikas, S. N., <i>et al.</i> , "Treatment of Resistant Rheumatoid Arthritis by Intra-Articular Infliximab Injections: A Pilot Study," <i>Ann. Rheum. Dis.</i> , downloaded from ard.bmjournals.com on 2 November 2005, <a href="http://www.annrheumdis.com">www.annrheumdis.com</a> 63: 102-103 (2004).	
AW11	Olmarker, K. and Rydevik, B., "Selective Inhibition of Tumor Necrosis Factor- $\alpha$ Prevents Nucleus Pulposus-Induced Thrombus Formation, Intraneural Edema, and Reduction of Nerve Conduction Velocity," <i>Spine</i> , 26(8): 863-869 (2001).	
AX11	Pacifici, R., "Editorial: Cytokines, Estrogen, and Postmenopausal Osteoporosis-The Second Decade," <i>Endocrinology</i> , 139(6):2659-2661 (1998).	
AY11	Pargellis, C. <i>et al.</i> , "Inhibition of p38 MAP Kinase by Utilizing a Novel Allosteric Binding Site," <i>Nature Structural Biology</i> , 9(4): 268-272 (2002).	
AZ11	Pederson, A.W. <i>et al.</i> , "Thermal Assembly of a Biomimetic Mineral/Collagen Composite," <i>Biomaterials</i> , 24:4881-4890 (2003).	

EXAMINER	DATE CONSIDERED
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PTO-1449 REPRODUCED  <b>SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION</b>  <b>March 15, 2006</b>  (Use several sheets if necessary)	ATTORNEY DOCKET NO. 3518.1012-005		APPLICATION NO. 10/714,594	
	FIRST NAMED INVENTOR Mohamed Attawia		FILING DATE November 14, 2003	
	EXAMINER Standley, Steven H.	CONFIRMATION NO. 3230	GROUP 1649	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)	
AR12	Peppel, K. <i>et al.</i> "A Tumor Necrosis Factor (TNF) Receptor-IgG Heavy Chain Chimeric Protein as a Bivalent Antagonist of TNF Activity," <i>J. Exp. Med.</i> , 174:1483-1489 (1991).
AS12	Rodan, G.A. <i>et al.</i> , "Therapeutic Approaches to Bone Diseases," <i>Science</i> , 289:1508-1514 (2000).
AT12	Schall, T. <i>et al.</i> , "Molecular Cloning and Expression of a Receptor for Human Tumor Necrosis Factor," <i>Cell</i> , 61:361-370 (1990).
AU12	Schatteman, L., <i>et al.</i> , "Treatment of Refractory Inflammatory Monoarthritis in Ankylosing Spondylitis by Intraarticular Injection of Infliximab," <i>J. Of Rheum.</i> , 33:1, pp. 82-85 (2006).
AV12	Stern, S., <i>et al.</i> , "Human Intervertebral Disc Cell Culture for Disc Disorders," <i>Clin. Orthop.</i> , 419:238-244 (2004).
AW12	Takegami, K., <i>et al.</i> , "Osteogenic Protein-1 Enhances Matrix Replenishment by Intervertebral Disc Cells Previously Exposed to Interleukin-1," <i>Spine</i> , 27(12):1318-1325 (2002).
AX12	Tobinick, E.L. and Davoodifar, S., "Perispinal TNF-alpha Inhibition for Discogenic Pain," <i>Swiss Med. Weekly</i> , 133:170-177 (2003).
AY12	Tobinick, E.L., "Targeted Etanercept for Discogenic Neck Pain: Uncontrolled, Open-Label Results in Two Adults," <i>Clin. Ther.</i> , 25(4):1211-1218 (2003).
AZ12	Wittenberg, R.H., <i>et al.</i> , "In Vitro Release of Prostaglandins and Leukotrienes From Synovial Tissue, Cartilage, and Bone in Degenerative Joint Diseases," <i>Arthritis Rheum.</i> , 36(10):1444-1450 (1993).
AR13	Yabuki, S., <i>et al.</i> , "Prevention of Compartment Syndrome in Dorsal Root Ganglia Caused by Exposure to Nucleus Pulposus," <i>Spine</i> , 26(8):870-875 (2001).
AS13	Zhang, C., <i>et al.</i> , "Mitogen-activated Protein (MAP) Kinase Regulates Production of Tumor Necrosis Factor- $\alpha$ and Release of Arachidonic Acid in Mast Cells," <i>J. Biol. Chem.</i> , 272(20): 13397-13402 (1997).
AT13	<a href="http://arthritis.com/od/kneetreatments/g/viscosupplement_p.htm">http://arthritis.com/od/kneetreatments/g/viscosupplement_p.htm</a> , 12-09-2005.
AU13	Kozbor, D. and Roder, J.C., "The Production of Monoclonal Antibodies from Human Lymphocytes," <i>Immunology Today</i> , 4(3):72-79 (1983).

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
AV13	Lane, N.E., <i>et al.</i> , "Basic Fibroblast Growth Factor Forms New Trabeculae That Physically Connect with Pre-Existing Trabeculae, and this New Bone is Maintained With an Anti-Resorptive Agent and Enhanced With an Anabolic Agent in an Osteopenic Rat Model," <i>Osteoporos Int</i> , 14: 374-382 (2003).	
AW13	Tobinick, E.L., "Targeted Etanercept for Treatment-Refractory Pain Due to Bone Metastasis: Two Case Reports," <i>Clinical Therapeutics</i> , 25(8):2279-2288 (2003).	
AX13	Vahle, J.L., <i>et al.</i> , "Skeletal Changes in Rats Given Daily Subcutaneous Injections of Recombinant Human Parathyroid Hormone (1-34) for 2 Years and Relevance to Human Safety," <i>Toxicologic Pathology</i> , 30(3):312-321 (2002).	
AY13	Yaffe, A., <i>et al.</i> , "Combined Local Application of Tetracycline and Bisphosphonate Reduces Alveolar Bone Resorption in Rats," <i>J Periodontol</i> , 74(7):1038-1042 (2003).	

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